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RANKING MEMBER

One Hundred Ninth Congress
U.S. House of Representatives
Committee on Homeland Security
Washington, DC 20515

May 9, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt:

I am very concerned that the Department of Health and Human Services' policy for the procurement of anthrax vaccine for the Strategic National Stockpile (SNS) may expose the American people to unnecessary risk.

Public reports have indicated that the number of anthrax vaccine doses currently in the SNS stands at between zero and 500—a number that falls far short of being able to cover the threat to the American civilian population—because a new type of anthrax vaccine under development as part of Project BioShield has not yet completed the development and approval process. Indeed, it has been reported that not a single anthrax vaccine dose has been added to the SNS since September 11, 2001.

A contract was just announced on May 6, 2005 to deliver approximately 5 million doses of an older version of the anthrax vaccine that is already successfully developed, but it is unclear when this delivery will be made or why this number of doses was all that was requested. Additionally, a memorandum of understanding (MOU) with the Department of Defense permits use of its stockpile of anthrax vaccine in the event of a domestic national emergency, but it is unclear how this arrangement would work if the military required the vaccine for its own use.

The new type of anthrax vaccine under development in Project BioShield has some unique benefits, but is offered by only one manufacturer and is not yet approved by the Food and Drug Administration (FDA). I know that Project BioShield's purpose is to develop vaccines from an experimental stage, and I support efforts to develop new anthrax vaccines such as those offered by this unique technology. However, I am concerned about the possibility that if this new technology is not ultimately successful, or does not receive FDA approval, the SNS may be left without an adequate supply of anthrax vaccine in the case of an emergency. Even if a waiver of FDA approval was

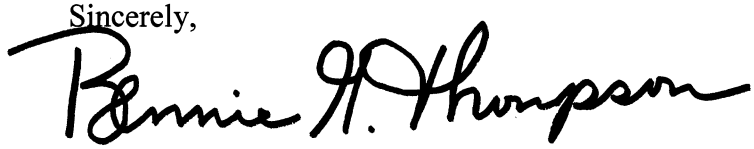
given due to a national emergency, it is unclear how quickly this new vaccine could be manufactured.

In order to clarify the level of anthrax protection in the SNS, I would appreciate you providing me with the following information:

1. What steps has HHS taken to contract for the purchase of anthrax vaccine doses for the SNS?
2. What are the number of anthrax vaccine doses ordered from each manufacturer for the SNS, and what number have been delivered?
3. What is the maximum number of anthrax vaccine doses of any type immediately available in the case of an emergency—either in the SNS or through outside agreements with other agencies or manufacturers?
4. What is the current progress of the development of the new anthrax vaccine in Project BioShield? For example, what is the status of the clinical trial testing and FDA approval of this vaccine?
5. In the event of an emergency, how quickly and in what number of doses can the manufacturer of the new anthrax vaccine supply the SNS?
6. If the FDA does not ultimately approve the new anthrax vaccine, does HHS intend to continue relying on that vaccine to meet the SNS' needs in the event of an emergency?
7. What is the reason you contracted for the purchase of 5 million doses of the older type of anthrax vaccine for the SNS, and why did it take so long before the need for these doses was recognized?

I would appreciate a timely response to my inquiries no later than June 1, 2005.

Sincerely,



Bennie G. Thompson
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House Committee on Homeland Security